

Draft Agenda: Stakeholder meeting to explore development of a certification scheme for certification against CWA 15793

The CEN Workshop Agreement (CWA) 15793 is an international laboratory biorisk management standard that sets requirements necessary to control risks associated with the handling or storage and disposal of biological agents and toxins in laboratories and facilities. CWA 15793 was delivered by CEN Workshop 31 which was proposed by the American Biological Safety Association, the European Biosafety Association and DNV, and which attracted participants from 76 organisations located in 24 countries as well as the WHO. Following three workshops held during 2007 and a public consultation exercise, consensus around the text was achieved in December 2007 and the standard was published in February 2008 and is available for download at: <http://www.cen.eu/cenorm/sectors/sectors/isss/cen+workshop+agreements/cwasnon-ict.asp>

CWA 15793 should enable organisations to do a number of things including allowing to “seek and achieve certification or verification of the biorisk management system by an independent third party”. An interest was expressed by the CEN workshop in the final meeting of 2007 for the development of guidelines which could form the basis of an accredited¹ certification² scheme. Such a scheme has the potential to meet, at least in part, the needs for independent assurance or oversight for a large number of stakeholders including the laboratories themselves, funding bodies, collaborating partners as well as government authorities. And there has been a growing interest in establishing an oversight mechanism for containment laboratories and other laboratories that work with dangerous pathogens and toxins. For example, in the United States the idea of a formal oversight system has surfaced in Congressional hearings³, appointed advisory committees⁴, and pending legislation⁵, among others. While in Europe the recently published CBRN Action Plan⁶ specifically calls on Member States to ensure laboratories are implementing appropriate standards such as CWA 15793.

To discuss and explore what approaches might be best to develop a professional and internationally recognised certification scheme based on the CWA 15793 DNV and Sandia Laboratories is organising a one day stakeholder meeting. This meeting will take place in Brussels on the day after the 1st workshop for the upcoming CWA guidelines.

¹ ISO 17000 defines accreditation as “third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks”

² ISO 17000 defines certification as “third-party attestation related to products, processes, systems or persons assessment except for conformity assessment bodies themselves, to which accreditation is applicable”

³<http://energycommerce.house.gov/Investigations/BSLLabs.shtml>

⁴Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight,; World at Risk report, WMD Commission, December 2008.

⁵WMD Prevention and Preparedness Act of 2009

⁶http://ec.europa.eu/justice_home/news/.../com_2009_0273_annexe_2_en.pdf

Goals for the meeting include:

- Gather information regarding the need for and interest in certification against CWA 15793
- Explore options regarding accreditation, certification, accredited certification, etc
- Identify a path to move forward, including what would need to be addressed in any certification guidelines

Tentative Agenda:

Place: CEN-CENELEC Management Centre
Avenue Marnix 17 - B-1000 Brussels
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<http://www.cen.eu/cen/AboutUs/CMC/Visitingus/Pages/default.aspx>

Date: 26th February, 2010

Time	Agenda point	Speaker/Facilitator
09:00	Welcome	Sandia and DNV
09:15	Stakeholder Introductions	All
09:45	CWA 15793 – Overview and next steps	Stefan Wagener – Public Health Agency of Canada
10:15	Laboratory Certification in Singapore.	Singapore Ministry of Health
10:35	ABSA Laboratory Accreditation Task Force	Chris Thompson – American Biological Safety Association
10:55	Towards laboratory biorisk certification in Germany?	Juergen Mertsching – Hannover Medical School
11:15	Coffee	
11:30	Certification – views from a conformity assessment body	Stephen McAdam - DNV
11:50	Management Systems Certification – the role of Accreditation bodies	Dutch Accreditation Council RvA/ Nederlands Normalisatie-instituut
12:20	Lunch	
13:00	Round table discussion regarding the strengths and weaknesses of different approaches	All – facilitated by Sandia
14:30	Coffee	
14:50	Identifying a way forward	All – facilitated by Sandia and DNV
16:30	Adjourn	